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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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08/594,175 01/31/96 WATKINS

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EXAMINER

HM42/0218

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KISHORE, R

PAPER NUMBER

1615

DATE MAILED:  
02/18/98

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 11-3-97
- ☒ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire - 3 - month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-10, 18-26 & 33-38 is/are pending in the application.
- ☐ Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-10, 18-26 & 33-38 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

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## **DETAILED ACTION**

### ***Claim Rejections - 35 U.S.C. § 112***

**1. The following is a quotation of the first paragraph of 35 U.S.C. 112:**

**The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

**2. Claims 1-10, 18-26 and 33-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is unclear from the specification whether ‘CATEZOMES’ as recited on page 6 of the specification are liposomes made of instant lipids and whether they are available commercially. Furthermore, if a fatty acid is already linked to the amine group as recited on page 6 of the specification, it is unclear how one can react another fatty acid with this compound to obtain a salt. The way the methodology is recited is confusing. The examples given do not clarify this confusion.**

**Applicants’ arguments have been fully considered, but are not found to be persuasive. This rejection is maintained since applicants have not clearly placed on record when the CATEZOMES were available to the public.**

**3. The following is a quotation of the second paragraph of 35 U.S.C. 112:**

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**The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

**4. Claims 33-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

**Said claims are indefinite since they depend from canceled claim 27. Also unclear is what applicants mean by 'fatty acid (A-ADDA) in claim 35.**

**It is unclear what applicants intend to convey by 'said buffer -----dispersing includes H<sub>2</sub>O' in claims 4 and 21. Buffers are made of water. 'Includes' is indefinite (also in claim 5-7, 9, 16, 17, 21-23, 26-27, and 33-35).**

**It is unclear what applicants intend to convey by 'applying sufficient ---- specified dimension' in claims 9 and 26. The terms sufficient and specified should be defined.**

**Claim 10 should recite adequately how the A-ADDA is prepared. The examiner suggests the deletion of 'around' in claims 10, 11, 27-28 and 'about' in claims 14, 31.**

**What is meant by 'occurrence of a triggering condition in claim 35? What are these conditions?**

**It is unclear where the proteins are and how they readily adhere as recited in claim 36.**

**It is unclear what 'controlling the salt bridge' in claim 37 means.**

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**These rejections are maintained since applicants have not adequately addressed the issues raised by the examiner.**

***Claim Rejections - 35 U.S.C. § 102***

**5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

**A person shall be entitled to a patent unless --**

**(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

**6. Claims 18-26, and 33-38 are rejected under 35 U.S.C. 102(b) as being anticipated by applicants' statements of prior art or EP 0 158 441.**

**As pointed out above, the specification on page 6 appear to indicate the commercial availability of the claimed liposomal composition. The method by which it is prepared has no significance in composition claims, in the absence of showing of patentably significant differences between the available product and the claimed product.**

**EP teaches liposomal composition containing instant lipid (note the abstract, and examples).**

**These rejections are maintained. The rejection over applicant's statements of prior art is maintained since applicants have not clearly placed on record, when the product CATEZOMES were available to the public.**

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**The rejection over EP is maintained since applicants' arguments that EP teaches phospholipid liposomes are not found to be persuasive. EP appears to teach liposomes containing the same claimed compound and instant 'comprising' does not exclude phospholipids in EP.**

**7. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).**

**A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the date of this final action.**

**8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.**

**The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.**

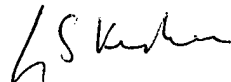
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**If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-5408.**

**Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].**

**All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.**

**Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-2351.**



**Gollamudi S. Kishore, Ph. D**

**Primary Examiner**

**Group 1500**